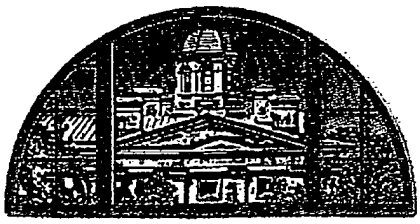

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FACSIMILE TRANSMITTAL COVER SHEET

DATE	:	September 16, 2008
TIME	:	
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TO	:	Commissioner for Patents
FACSIMILE NO.	:	(571) 273-8300
INVENTOR(S)	:	Winthrop D. Childers et al.
APPLICATION NO.	:	10/777,449
FILING DATE	:	February 11, 2004
CONFIRMATION NO.	:	4805
EXAMINER	:	Kristen C. Matter
GROUP ART UNIT	:	3771
FROM	:	Walter W. Karnstein, Esq.
ATTY REF. NO.	:	HPCC 3B3
NO. OF PAGES	:	35 (including cover sheet)
SPECIAL INSTRUCTIONS	:	***Attached is a DUPLICATE SUBMISSION to ensure receipt of Applicants' entire Appeal Brief which was originally filed by facsimile on September 15, 2008. It is unclear from Applicants' facsimile confirmation report whether the entire Appeal Brief was received by the Office.***

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P 1
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Serial No. A00J010002744
TC: 227326

Destination	Start Time	Time	Prints	Result	Note
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91571273830OPPPPP63	09-15 14:38	00:02:49	010/033	OK	HPCC 3B3

Note TMR: Timer TX, POL: Polling, ORG: Original Size Setting, FME: Frame Erase TX, MIX: Mixed Original TX, CALL: Manual TX, CSRC: CSRC, FWD: Forward, PC: PC-Fax, BND: Double-Sided Binding Direction, SP: Special Original, FCODE: F-Code, RTX: Re-TX, RLY: Relay, MBX: Confidential, BUL: Bulletin, SIP: SIP Fax, IPADR: IP Address Fax, I-FAX: Internet Fax

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HEWLETT-PACKARD COMPANY
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P.O. Box 272400
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PATENT APPLICATION

ATTORNEY DOCKET NO. 200209746-1

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Winthrop D. CHILDERS et al.
Confirmation No.: 4806
Application No.: 10/777,449
Examiner: Kristen O. MATTER
Filing Date: February 11, 2004
Group Art Unit: 3771

Title: MEDICAMENT DISPENSER

Mail Stop Appeal Brief-Patents
Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on ______________.

☒ The fee for filing this Appeal Brief is $510.00 (37 CFR 41.20).

☐ No Additional Fee Required.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☒ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $120 ☐ 2nd Month $460 ☒ 3rd Month $1050 ☐ 4th Month $1640

☐ The extension fee has already been filed in this application.

☐ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 1560 . At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

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Date of facsimile: September 15, 2008
Typed Name: Theresa Dawson
Signature: [signature]

Respectfully submitted,
Winthrop D. CHILDERS et al.
By [signature]
Walter W. KARNSTEIN
Attorney/Agent for Applicant(s)
Reg No.: 36,668
Date: September 15, 2008
Telephone: (303) 284-0000

Rev 10/07(AplBrief)

HEWLETT-PACKARD COMPANY
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PATENT APPLICATION

ATTORNEY DOCKET NO. 200309745-1

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Winthrop D. CHILDERS et al.

Confirmation No.: 4805

Application No.: 10/777,449

Examiner: Kristen C. MATTER

Filing Date: February 11, 2004

Group Art Unit: 3771

Title: MEDICAMENT DISPENSER

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Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on _____.

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(complete (a) or (b) as applicable)

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☒ I hereby certify that this paper is being transmitted to the Patent and Trademark Office facsimile number (571)273-8300.
Date of facsimile: September 15, 2008
Typed Name: Theresa Belland
Signature:

Respectfully submitted,
Winthrop D. CHILDERS et al.
By
Walter W. KARNSTEIN
Attorney/Agent for Applicant(s)
Reg No. : 35,565
Date : September 15, 2008
Telephone : (503) 224-6655

Rev 10/07(ApiBrief)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		Dated:	September 15, 2008
Winthrop D. CHILDERS et al.		HP Docket No.:	200309745-1
Serial No.:	10/777,449	Examiner:	Kristen C. MATTER
Filed:	February 11, 2004	Group Art Unit:	3771
For:	MEDICAMENT DISPENSER	Confirmation No.:	4805

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

S i r :

BRIEF OF APPELLANTS

This Brief is presented in opposition to the Examiner's rejection of claims 1 and 4-28 in the Final Office Action dated March 26, 2008 (hereinafter, "the Final Office Action").

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 20555 S.H. 249 Houston, TX 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. RELATED APPEALS AND INTERFERENCES

Appellants and the undersigned attorneys are not aware of any appeals or any interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1 and 4-28 are pending in the application. Claims 2 and 3 are canceled. Claims 1 and 4-28 stand rejected.

IV. STATUS OF AMENDMENTS

The present application was filed on February 11, 2004 with original claims 1-28. In the response dated October 3, 2007, claims 1, 2, 15, 27, and 28 were amended. In the response dated January 29, 2008, claims 2 and 3 were canceled, and claims 1, 4, 5, 14, 15, and 28 were amended. In the response dated May 20, 2008 the claims were not amended further.

Claims 1 and 4-28 as amended in the response dated January 29, 2008 are the claims at issue in this appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The summary is set forth in exemplary embodiments. Discussions of selected elements and recitations of claimed subject matter can be found at least at the cited locations in the specifications and drawings. The claims of the present application are directed to medicament dispensers, such as inhalers, that include a medicament supply, an ejector, and a controller that is configured to actuate the ejector, where the controller is configured to use an operational parameter to produce a plurality of medicament drops having a target drop characteristic, and where the operational parameter includes a correction factor that is based on a performance characteristic of the ejector.

1. Independent claim 1

Claim 1 is directed to a medicament dispenser 10, that includes a medicament supply 24, and a medicament ejector 26 that is in fluid communication with the medicament supply (see Figs. 1 and 2; the specification at page 3, lines 7-20; and claim 1 as originally filed). The medicament dispenser 10 also includes an accumulator 30 that is in fluid communication with the ejector 26, and a sensor 32 configured to sense the medicament pressure within the accumulator. A valve 34 disposed between the medicament supply and the accumulator is configured to open and close in response to the medicament pressure sensed by sensor 32 within the accumulator 30 in order to regulate medicament pressure at the ejector 26 (see page 3, lines 12-19).

Ejector 26 exhibits a selected performance characteristic, and the medicament dispenser 10 includes a controller 28 that is configured to actuate ejector 26 using an operational parameter that includes a correction factor based on the selected

performance characteristic, in order to produce a plurality of medicament drops having the desired, or target drop characteristics (see page 9, line 5 to page 12, line 15).

Selected performance characteristics may include ejected drop size, measured as volume, or drop weight, or both (see page 9, lines 11-25). Selected operational parameters include ejector temperature, ejection frequency, medicament pressure, and the adjustment of some or all of the operational parameters results in subsequent, actuation of the inhaler producing an appropriate dosage of the fluid medicament (see page 11, line 20 to page 12, line 15).

1(a). Claim 4

Dependent claim 4 is directed to a medicament dispenser according to claim 1 that further includes a compliant member 52 that regulates the medicament pressure within the accumulator 30 (see Fig. 2; see page 5, line 15 to page 6, line 20).

1(b). Claim 5

Dependent claim 5 is directed to a medicament dispenser according to claim 1, where controller 28 is configured to operate valve 34 in order to increase the medicament pressure within accumulator 30 (see page 3, lines 12-19).

2. Independent claim 14

Independent claim 14 is directed to an inhaler 10 that includes a medicament supply 24, a medicament accumulator 30 in fluid communication with medicament supply 24. The medicament accumulator 30 includes a sensor 32 that is configured to sense a medicament pressure within the medicament accumulator, and a compliant member 52 that is fluidically coupled to the medicament accumulator (see Fig 2; see

page 3, line 7 to page 6, line 20). The inhaler further includes a valve 34 disposed intermediate the medicament supply 24 and the medicament accumulator 30 (see page 6, line 21 to page 7, line 12).

The inhaler further includes an ejector 26 that is in fluid communication with the medicament accumulator 30, a controller 28 that is configured to apply a correction factor to a selected operational parameter of ejector 26, where the correction factor is determined by a performance characteristic of ejector 26 (see page 9, line 5 to page 12, line 15).

3. Independent claim 15

Independent claim 15 is directed to a method of calibrating a medicament inhaler to achieve a target output characteristic, where the medicament inhaler 10 includes a medicament supply 24, a medicament accumulator 30 in fluid communication with the medicament supply 24, a sensor 32 configured to sense medicament pressure within the accumulator 30, a valve 34 intermediate the medicament supply and the medicament accumulator 30, a medicament ejector 26 in fluid communication with the medicament accumulator 30, and a controller 28 configured to open and close valve 34 in response to a medicament pressure sensed by sensor 32 within accumulator 30.

The claimed method is depicted in flow chart 90 of Fig. 5, and described at page 13, line 30 to page 14, line 4, and includes manufacturing the medicament inhaler at 92, characterizing the output of the inhaler at 94, comparing the characterized output to the target output characteristic at 96, determining a correction factor to produce the target

output from the inhaler at 98, and configuring the controller to apply the correction factor to the inhaler at 100.

4. Independent claim 28

Independent claim 28 is directed to an inhaler 10 (see Figs. 2 and 3), that includes a means for supplying fluid medicament 24 (see page 8, lines 3-23), a means for ejecting fluid medicament 26 (see page 3, line 20 to page 4, line 11), where the ejecting means has a performance characteristic, a means for accumulating fluid medicament 30 in fluid communication with the ejector means 26 including a means for sensing fluid medicament pressure 32 within the accumulator means (see page 5, line 15 to page 6, line 20, a means for regulating 34 an addition of medicament to the accumulator means 30 from the fluid medicament supply means 26 in response to the pressure sensing means 32 (see page 6, line 21 to page 7, line 22), and a means for actuating 28 the ejector means 26 using an operational parameter calculated from the performance characteristic of the ejector means (see page 4, line 21 to page 5, line 10).

VI. GROUNDS OF REJECTION

In the Office Action dated March 26, 2008, claims 1 and 4-28 were rejected. More specifically,

- Claims 1, 4, 5, 8-15, and 21-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (U.S. Patent No. 6,234,167) in view of Poole (U.S. Patent No. 6,158,431); and
- Claims 6, 7, and 16-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. and Poole, as applied to claims 1, 4-5, 8-15, and 21-28, and further in view of Poole et al. (U.S. Patent No. 5,278,626).

VII. ARGUMENT

VII. (A) Obviousness under 35 U.S.C. § 103

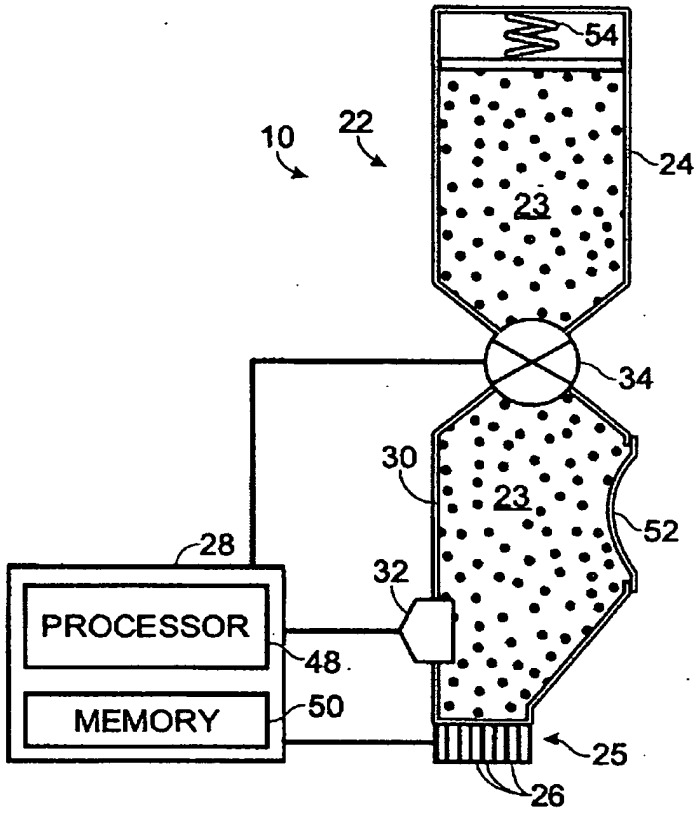
The Examiner bears the burden of factually supporting any *prima facie* conclusion of obviousness. To reach a proper obviousness determination, the Examiner must consider the prior art from the point of view of a person of ordinary skill in the art at a time when the invention was unknown and just before it was made. The Examiner must then make a determination as to whether the claimed invention as a whole would have been obvious at that time to that person. Knowledge of the Appellants' disclosure must be put aside in reaching this determination, in order to avoid the danger of impermissible hindsight.

The *prima facie* case of obviousness must be reached on the basis of the facts gleaned from the prior art. *Prima facie* obviousness cannot be established with mere conclusory statements. Rather, the Examiner must provide some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

VII. (B) The Claimed Invention

The application under appeal is directed to dispensers for medication, such as inhalers, and their calibration to a target output characteristic. An exemplary dispenser is depicted in Fig. 2 of the application, reproduced below:

Fig. 2



The claimed dispenser (10) includes a medicament supply (24), an ejector (26) that is in fluid communication with the medicament supply, an accumulator (30) that is in fluid communication with the ejector, a sensor (32) that senses the pressure of the medicament within the accumulator, and a valve (34) between the medicament supply and the accumulator, where the valve opens and closes in response to the sensed pressure within the accumulator in order to regulate the medicament pressure at the ejector.

The claimed dispenser further includes a controller (28) that actuates the ejector using an operational parameter in order to produce a plurality of medicament drops having desired drop characteristics, where the operational parameter used includes a correction factor based on the performance characteristic of the ejector.

Selected correction factors which may be applied include a corrected drop ejection frequency, a corrected number of drops ejected, a corrected medicament fluid pressure, a corrected ejector temperature, and/or a corrected drop ejection frequency.

In particular, the claimed dispensers include a medicament accumulator, as shown at 30 in Fig. 2. The accumulator serves to provide fluid medicament to the ejector, and to regulate the pressure of the medicament at the ejector:

Appellants respectfully submit that the Examiner has failed to establish the *prima facie* obviousness of the claimed dispensers and methods.

VII. (C) **Claims 1, 4, 5, 8-15, and 21-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. (U.S. Patent No. 6,234,167) in view of Poole (U.S. Patent No. 6,158,431).**

The Examiner asserts that Cox et al. disclose an inhaler having a medicament supply (37), an ejector (29, 33), an accumulator (tube 27), and a valve intermediate the medicament supply and the accumulator. The inhaler of Cox et al. is shown below:

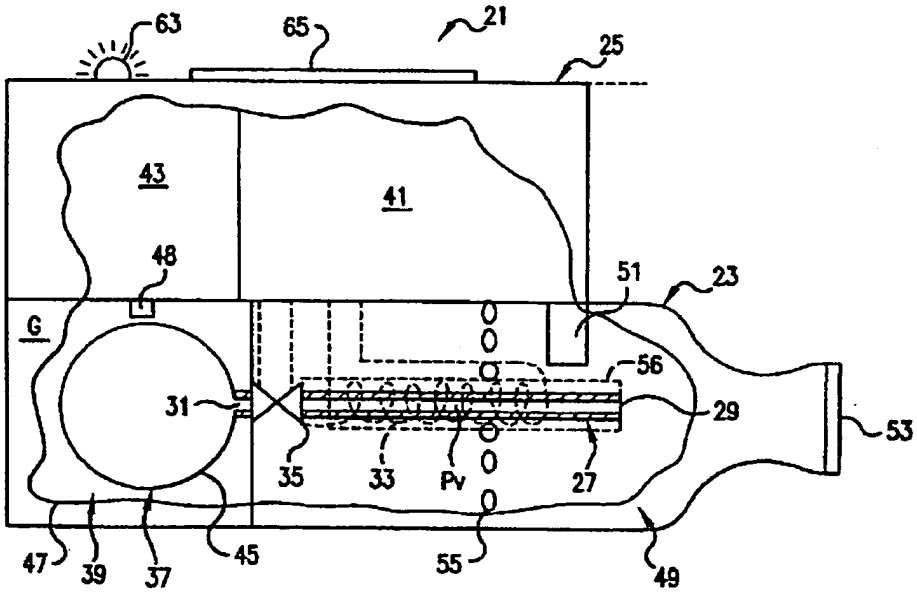


FIG.1

The Cox inhaler operates as follows: The supply of material to be delivered by the inhaler is contained within a flexible container 45. Container 45 is disposed within a pressurized chamber 47, and a pressurized gas G sealed in chamber 47 surrounds flexible container 45, and thereby pressurizes the material to be delivered.

Activation of the inhaler results in the opening of valve 35, which separates container 45 from open-ended tube 27. Activation also results in power being supplied to heater 33 surrounding open-ended tube 27, causing it to heat up to its desired operating temperature. The pressure of the gas G compresses the flexible container 45, expressing material into tube 27 through the second end 31. The newly-deposited material is then heated by heater 33 to a vaporization temperature. As the material volatilizes, the volatilized material expands out of the free end 29 of the tube (see col. 4, lines 25 to col. 5, line 26).

VII. (C)(1) The Cited References Fail to Disclose Every Element of the Rejected Claims

Claims 1, 4, 5, 8-15, and 21-28

In formulating the rejection, the Examiner asserts that the combination of heater 33 and open end 29 correspond to the recited ejector, and that tube 27 corresponds to the recited accumulator. In particular, the Examiner states that "tube (27) is considered an accumulator as defined by the instant specification on page 3 as a volume in fluid communication with the ejectors" (see the Action dated March 26, 2008 at page 2, lines 21-22). Appellants disagree, and respectfully suggest that the Examiner is misapplying the disclosure of Cox et al., as well as misconstruing the dispenser of claim 1.

The Examiner has cited the specification in support of the definition of the accumulator as "a volume in fluid communication with the ejectors". However, the specification goes into greater detail as to the function of the accumulator in the claimed dispenser:

> The controller may be configured to regulate the pressure of medicament at the ejectors. For example, the inhaler may include an accumulator 30 that defines an accumulator volume that may be in fluid communication with the ejectors, a sensor 32 that may be configured to sense pressure of the fluid within the accumulator, and a valve mechanism 34 that may be in fluid communication with the medicament supply. Controller 28 may be configured to operate valve mechanism 34 in response to the sensed pressure within the accumulator, thereby regulating pressure at the ejectors. (page 3, lines 12-19; emphasis added)

Appellants disagree with the Examiner's characterization of the combination of heater 33 and open end 29 as corresponding to the ejector of the claimed dispenser, while tube 27 is identified as the accumulator. The accumulator functions to regulate pressure at the ejector, and an open-ended tube cannot regulate the pressure within the tube. This is particularly true as Cox et al. explicitly teaches that the material deposited into the tube volatilizes and leaves tube 27 via the open end 29 as soon as it has volatilized. An open system simply cannot be held at a desired pressure, whether that pressure is positive or negative.

The Examiner has asserted that Cox discloses a "pressure drop sensing device" to sense the pressure in the accumulator. Appellants disagree that Cox discloses a pressure sensor that is "configured to sense medicament pressure within the accumulator" as recited by claim 1. The sensor relied upon by the Examiner is shown at 51 in Fig. 1 of Cox, clearly outside tube 27. Cox simply indicates that sensor 51 determines "a predetermined pressure drop" "proximate the first end 29 of the tube 27" (col. 6, lines 32-45).

The sensor of Cox explicitly senses a relative pressure drop, not an absolute pressure. The sensor of Cox also detects this pressure drop not within tube 27, which the Examiner indicates is an accumulator, but entirely outside tube 27, near the open end 29 of the tube. Appellants respectfully suggest that the sensor of Cox et al. is not configured to detect the pressure within an accumulator.

Furthermore, claim 1 recites "a valve intermediate the medicament supply and the accumulator, the valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector." Appellants strongly suggest that opening valve 35 to introduce an initially nonvolatile substance into tube 27 cannot regulate the pressure within the tube, at least in part because a nonvolatile substance will not significantly effect the pressure within the tube until it is volatilized, at which time tube 27 is no longer an accumulator, but becomes an ejector. Furthermore, as stated above, the pressure within tube 27 cannot be regulated by opening valve 35, as tube 27 is open-ended.

Claims 4 and 14

With particular respect to claims 4 and 14, Appellants note that the claimed dispenser further includes a "compliant member that regulates pressure within the accumulator" and "a compliant member fluidically coupled to the medicament accumulator," respectively. Appellants respectfully suggest that the Cox et al. inhaler fails to disclose a compliant member that is disposed to regulate pressure within an accumulator. The Examiner has identified flexible container 45, which Cox et al. discloses as containing the material to be dispensed, as corresponding to the claimed

compliant member. Appellants respectfully suggest that flexible container 45 cannot function as the compliant member, for at least the following reasons.

The relationship between the compliant member and accumulator pressure is set out in the specification at page 5, lines 15-25:

> The medicament pressure within accumulator 30 may be at least partially regulated by fluidically coupling the accumulator with a compliant member 52, as shown in Fig. 2. Compliant member 52 may be resilient (and/or elastic) so that as the inhaler is activated, and medicament is ejected from the ejection apparatus and pressure within the accumulator decreases, the compliant member 52 may deform elastically into the accumulator. This deformation may serve to regulate the back pressure within the accumulator. Alternatively, where the regulated pressure is a positive pressure, the compliant member may be deformed elastically outward during charging of the accumulator from the medicament supply, such that the compliant member relaxes as the inhaler is activated and accumulator pressure decreases. (emphasis added)

In particular, in order to function as recited in claim 4, the compliant member must be fluidically coupled with the accumulator volume, such that application of negative pressure can be achieved by elastic deformation of the membrane into the accumulator, while positive pressure may be applied by outward deformation of the membrane.

As flexible container 45 of Cox et al. is isolated from the putative accumulator volume, container 45 cannot actively regulate the pressure within the accumulator. Of course, as discussed above, as tube 27 is open-ended there is no way to regulate the pressure within tube 27.

Claims 15-27

With particular respect to method claims 15-27, the Examiner asserts that "the modified Cox et al. device has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so" (see the Office Action dated March 26, 2008 at page 4, lines 5-6). However, the method of claim 15 recites a method for calibrating a medicament inhaler to a target output characteristic, where the recited medicament inhaler includes a medicament supply, a medicament accumulator in fluid communication with the medicament supply, a sensor configured to sense medicament pressure within the accumulator, a valve intermediate the medicament supply and the medicament accumulator, a medicament ejector in fluid communication with the medicament accumulator, and a controller configured to open and close the valve in response to a sensed medicament pressure within the accumulator.

As discussed above, and for at least the reasons that the Cox et al. reference fails to disclose an inhaler having an accumulator, a sensor configured to sense medicament pressure within the accumulator, or a dispenser capable of regulating the pressure within the accumulator by opening and closing a valve in response to a sensed medicament pressure within the accumulator, Appellants suggest that the Cox et al. reference fails to disclose the inhaler of claim 15, and therefore fails to establish the *prima facie* obviousness of claim 15, and claims 16-27 which depend from claim 15.

Appellants respectfully suggest that, for at least the above reasons, Cox et al. fails to disclose the claimed dispenser of claims 1, 4, 5, 8-14, and 28, or the methods of calibrating of claims 15-27, as Cox et al. fails to disclose each and every element of the

rejected claims. The Examiner has asserted that "one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." (see the Office Action dated March 26, 2008 at page 6, lines 6-10). However, Appellants respectfully suggest that where the Examiner has stated that the Poole reference is "cited merely as evidence that it is well known that determining volume from droplet diameter in an inhaler is well known in the art" (see the Office Action dated March 26, 2008 at page 6, lines 4-6), that Appellants are therefore entitled to rely upon the presumption that Cox et al. is cited for its sole disclosure of the structural elements of the recited dispenser.

VII. (C)(2) No Motivation to Combine the Cited References

Appellants further suggest that the Examiner has failed to provide sufficient motivation to combine the Cox et al. and Poole references. The Cox et al. reference discloses an inhaler that generates an aerosol for inhalation by heating a volatile material. Poole, on the other hand, creates droplets by forcing liquid through orifices in a piezoelectric oscillator. The methods disclosed by Poole, if implemented into the Cox et al. device, would simply force the substance of interest into a tube and permit a heater to volatilize the substance so that it expands out of the tube.

As the methods of droplet generation in the cited references are distinct, the methods of regulating the size of generated droplets described by Poole, such as by changing the oscillation frequency of the piezoelectric driver (see col. 11, lines 8-16), are not interchangeable with the methods of Cox. As such, one of skill in the art seeking to modify the inhaler of Cox would not be led to use the delivery system of Poole.

Furthermore, one of skill in the art seeking to modify the dispenser of Poole would not use the inhaler of Cox, as Cox does not permit the user to modify generated droplet size, whereas the mechanism of Poole does.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious (MPEP § 2143.01).

For at least these reasons, Appellants respectfully suggest that claims 1, 4, 5, 8-15, and 21-28 are not rendered unpatentable by Cox et al. and Poole, and Appellants request that the rejection of claims 1, 4, 5, 8-15, and 21-28 under 35 U.S.C. § 103 be reversed.

VII. (D) Claims 6, 7, and 16-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cox et al. and Poole, as applied to claims 1, 4-5, 8-15, and 21-28, and further in view of Poole et al. (U.S. Patent No. 5,278,626).

The Examiner has asserted that Cox et al. as modified by Poole does not explicitly disclose the determination of ejected drop volume or weight, but that it would have been obvious to one of ordinary skill in the art at the time of the invention to use drop volumes or weight as taught by Poole, and drop volumes determined from droplet diameter as taught by Poole et al., for a more accurate determination of the amount of medication being delivered to the patient with each drop. Appellants respectfully disagree.

For at least the reasons discussed above, Appellants suggest that the combination of Cox et al. and Poole is improper, and that even in combination the cited

references fail to disclose each and every element of the claimed dispenser or method of calibrating. Appellants further suggest that even in combination with Poole et al., the cited references fail to establish the *prima facie* obviousness of the rejected claims.

The Examiner asserts that the modified device disclosed by Cox et al., Poole and Poole et al. has all of the structural limitations needed to perform the recited method steps, and is fully capable of doing so. Appellants respectfully disagree. As discussed above, even in combination, the cited references fail to disclose an inhaler having an accumulator, a sensor configured to sense medicament pressure within the accumulator, or a dispenser capable of regulating the pressure within the accumulator by opening and closing a valve in response to a sensed medicament pressure within the accumulator.

Claims 16-20

However, even if the combination of Cox et al., Poole, and Poole et al. were to generate a device capable of carrying out the method of claims 16-20, the Examiner is employing the wrong standard in determining the obviousness of the method claims. The fact that the references could be combined or modified does not establish *prima facie* obviousness unless the results would have been predictable to one of ordinary skill in the art. Appellants respectfully suggest that the references fail to provide sufficient guidance that a skilled artisan would be led to the method of claims 16-20, much less arrive at the claimed method with a reasonable expectation of its success.

For at least these reasons, Appellants respectfully suggest that claims 6, 7, and 16-20 are not rendered unpatentable by Cox et al., Poole, and Poole et al., and

Appellants request that the rejection of claims 6, 7, and 16-20 under 35 U.S.C. § 103 be withdrawn.

VII. (E) Conclusion

Appellants suggest that the references cited by the Examiner have failed to establish the *prima facie* obviousness of the rejected claims, and that the claimed invention is therefore not rendered unpatentable under 35 U.S.C. § 103(a).

Accordingly, the rejection of all pending claims should be reversed.

VIII. Claims Appendix

1. (Previously Presented) A medicament dispenser, comprising:

a medicament supply;

an ejector having a performance characteristic, the ejector being in fluid communication with the medicament supply;

an accumulator in fluid communication with the ejector;

a sensor configured to sense medicament pressure within the accumulator;

a valve intermediate the medicament supply and the accumulator, the valve configured to open and close in response to a sensed medicament pressure within the accumulator to regulate medicament pressure at the ejector;

and

a controller configured to actuate the ejector using an operational parameter to produce a plurality of medicament drops having target drop characteristics, the operational parameter including a correction factor based on the performance characteristic of the ejector.

2. (Canceled)

3. (Canceled)

4. (Previously Presented) The medicament dispenser of claim 1, further comprising a compliant member that regulates pressure within the accumulator.

5. (Previously Presented) The medicament dispenser of claim 1, wherein the controller is configured to operate the valve to increase the medicament pressure within the accumulator.

6. (Original) The medicament dispenser of claim 1, wherein the performance characteristic of the ejector includes ejected drop volume.

7. (Original) The medicament dispenser of claim 1, wherein the performance characteristic of the ejector includes ejected drop weight.

8. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes drop ejection frequency.

9. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes number of drops ejected.

10. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes medicament pressure.

11. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes ejector temperature.

12. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes a static correction factor.

13. (Original) The medicament dispenser of claim 1, wherein the operational parameter includes a dynamic correction factor.

14. (Previously Presented) An inhaler, comprising:

a medicament supply;

a medicament accumulator in fluid communication with the medicament supply;

a compliant member fluidically coupled to the medicament accumulator;

a valve intermediate the medicament supply and the medicament accumulator;

a sensor configured to sense a medicament pressure within the medicament accumulator;

an ejector in fluid communication with the medicament accumulator, wherein the ejector has a performance characteristic; and

a controller configured to apply a correction factor to an operational parameter of the ejector, wherein the correction factor is determined by the performance characteristic of the ejector.

15. (Previously Presented) A method of calibrating a medicament inhaler to a target output characteristic, the medicament inhaler having a medicament supply, a medicament accumulator in fluid communication with the medicament supply, a sensor configured to sense medicament pressure within the accumulator, a valve intermediate the medicament supply and the medicament accumulator, a medicament ejector in fluid communication with the medicament accumulator, and a controller configured to open and close the valve in response to a sensed medicament pressure within the accumulator, the method comprising:

manufacturing the medicament inhaler;

characterizing the output of the inhaler;

comparing the characterized output to the target output characteristic;

determining a correction factor to produce the target output from the inhaler; and

configuring the controller to apply the correction factor to the inhaler.

16. (Original) The method of claim 15, wherein characterizing the output of the inhaler includes determining an ejected drop weight.

17. (Original) The method of claim 16, wherein characterizing the output of the inhaler includes determining the ejected drop weight as a function of drop frequency.

18. (Original) The method of claim 16, wherein characterizing the output of the inhaler includes determining the ejected drop weight as a function of medicament ejector temperature.

19. (Original) The method of claim 15, wherein comparing the characterized output to the target output characteristic includes comparing a determined ejected drop weight to a target drop weight.

20. (Original) The method of claim 15, wherein determining a correction factor includes determining a corrected drop weight.

21. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a static correction factor.

22. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a dynamic correction factor.

23. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected drop ejection frequency.

24. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected number of drops ejected.

25. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected medicament fluid pressure.

26. (Original) The method of claim 15, wherein configuring the controller to apply the correction factor to the inhaler includes configuring the controller to apply a corrected ejector temperature.

27. (Previously Presented) The method of claim 26, wherein configuring the controller to apply the corrected ejector temperature includes configuring the controller to apply a corrected drop ejection frequency.

28. (Previously Presented) An inhaler, comprising:

a means for supplying fluid medicament;

a means for ejecting fluid medicament, the means having a performance characteristic;

a means for accumulating fluid medicament in fluid communication with the ejector means;

a means for sensing fluid medicament pressure within the accumulator means;

a means for regulating an addition of medicament to the accumulator means from the fluid medicament supply means in response to the pressure sensing means; and

a means for actuating the ejector means using an operational parameter calculated from the performance characteristic of the ejector means.

IX. Evidence Appendix

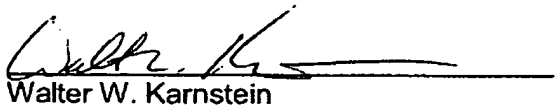
None.

X. Related Proceedings Appendix

None.

Respectfully submitted,

KOLISCH HARTWELL, P.C.



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Theresa Belland